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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,947	01/04/2006	Toru Myogadani	P28635	5817
7055 7590 09/20/2007 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			EXAMINER BITAR, NANCY	
			ART UNIT 2624	PAPER NUMBER
			NOTIFICATION DATE 09/20/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,947	<b>Applicant(s)</b> MYOGADANI ET AL.	
	<b>Examiner</b> Nancy Bitar	<b>Art Unit</b> 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>01/04/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. Figure 8 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claim 1, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Claim 2-5 variously depends on claim 1 and are thus indefinite.

### ***Information Disclosure Statement***

3. The information disclosure statement filed 01/04/2006 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there is no English translation or English abstract to the following documents (JP 11-044509; JP 140459,JP

170761). It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

#### ***Oath/Declaration***

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not include the notary's signature, or the notary's signature is in the wrong place.

#### **Examiner Notes**

5. Examiner cites particular columns and line numbers in the references as applied to the claims below for the convenience of the applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested that, in preparing responses, the applicant fully consider the

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references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shen et al (US 5594808) in view of Dupinet et al (US 5872860) and further in view of Yamamoto et al (JP 61-007426).

As to claim 1, Shen et al teaches an optical inspection apparatus for inspecting the presence or absence of an object to be inspected that causes optical changes such as white turbidity and white sedimentation; or fluorescence for a sample charged in a sample tube, including a reaction block (rack) in which a plurality of arrangement holes for standing and arranging sample tubes are formed ((optical inspection device that inspects the presence or absence and status of a coagulation reaction in samples respectively inserted into a plurality of sample tubes aligned in parallel , figure 2, column 6, lines 25-35), a light emitting portion ( a light source 36b, note that note that holding means 12 includes a base 32 and frame 34 and the light source 14 includes

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two constant fluorescence tubes 36a and 36b) for irradiating an inspection light to the respective sample tubes through observation holes formed to the lateral surface or holes formed in the bottom of the reaction block ( column 5, lines 40-53; note that the light source projects light via a transparent surface equivalent to the observation window hole formed in the side surface of the reaction block ( see figure 11 and 12), an image pick-up camera ( camera 44)for photographing each of the sample tubes passing through the observation holes ( note that image camera 44 acquires images of the plurality of sample tubes all at once ) , and an operation processing device for measuring the optical change( preprocessor 56) caused in the sample tubes based on the luminance distribution or the chromaticity distribution of image data photographed by the image pick-up camera ( camera 44).

While Shen meets a number of the limitations of the claimed invention, as pointed out more fully above, Shen fails to specifically teach the irradiating an inspection light to the respective sample tubes through observation holes formed to the lateral surface.

Specifically, Dupinet et al. teaches the opaque area reflects the light incident from the side of cassette on which the pixel array is located, but blocks the transmission of light from the opposite side. By measuring the gray value of the image on the pixel array of this opaque region, the intensity of light from the pixel side of the cassette can be determined. It would have been obvious to one of ordinary skill in the art to use the aforesaid block that is provided with plurality of observation holes in the side in Shen system 10 in order to simplify the assembling operation. Therefore, the claimed

invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

The limitations of claims 2-5 has been addressed above except for the following:

Yamamoto teaches an optical inspection apparatus according to claim 1, wherein an excitation light at a wavelength corresponding to a fluorescent material mixed previously with the sample is irradiated as an inspection light and the fluorescence caused in the sample is measured as an optical change based on the luminance distribution or the chromaticity distribution obtained in the image data (the immune coagulation reaction measurement injecting a fluorescently labeled antibody as a reaction reagent and detecting the component formed as a result of the reaction by irradiating with excitation light and measuring the fluorescence, figures 1-2) .

Moreover, Yamamoto teaches an optical inspection apparatus according to claim 1, wherein the light emitting devices are disposed at the bottom to the respective arranged holes by driving and moving the light path switching mechanism 18' to the outside of the light path (see abstract, figures 5-6) It is obvious to arrange the optical system of Shen so that excitation light is irradiated from the bottom of the cell and fluorescent light is detected from the side, thus measuring required light among the emitted light . Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yamamoto et al (US 5,093,271) Is cited to teach quantitative analysis for an antigen (or an antibody) which comprises allowing said antigen (or antibody) to react with an antibody (or antigen) supported on an insoluble carrier of fine particle size, irradiating light onto the resultant antigen-antibody complex, and measuring its absorbance at a specific wavelength; particularly a method that can measure the amount of an antigen or antibody in samples taken from living bodies simply and at a high sensitivity.

Cook et al (US 6,175,750) is cited to teach calibration apparatus comprises an optical filter that is placed between the light source used in the imaging apparatus and the object under analysis, and a calibration module. The filter is fabricated such that when the light is passed through the filter, an image is projected onto the focal plane where imaging is to take place within the object. The image projected by the filter comprises a plurality of areas, each having a different known optical density. For each area, the calibration module measures the intensity of the light reflected from the area and maps the light intensity measurement to the optical density known to be present at the area. This correspondence of light intensity measurements and known optical densities is then used to calibrate the reflected spectral imaging apparatus

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Bitar whose telephone number is 571-270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).



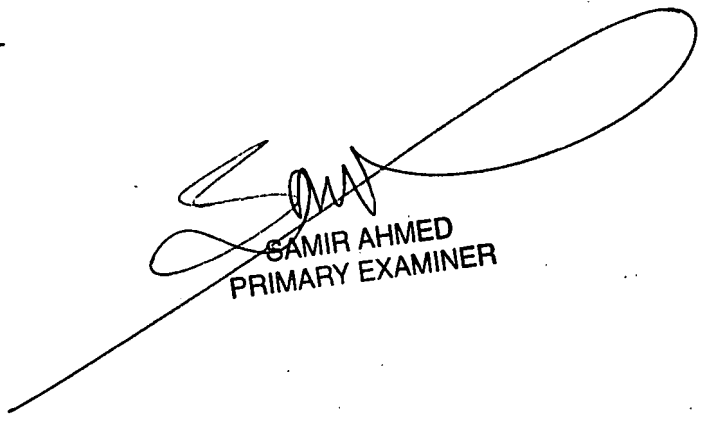
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Samir Ahmed can be reached on 571-272-7413. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nancy Bitar

9/5/2007



SAMIR AHMED  
PRIMARY EXAMINER